Butler, Jennie C

From: Gross, Mary
Sent: Friday, August 09, 2002 11:06 AM
To: Butler, Jennie C
Subject: FW: FDA Public Meeting -- Barcoding Human Drugs and Biologics

-----Original Message-----
From: Joseph Cranston [mailto:Joseph_Cranston@ama-assn.org]
Sent: Tuesday, July 16, 2002 11:52 AM
To: GrossM@cder.fda.gov
Subject: RE: FDA Public Meeting -- Barcoding Human Drugs and Biologics

Mary. I sent a summary last Wednesday, but I've reattached it to this email As I noted in that email, I anticipate only about 7 minutes to deliver the AMA's presentation

Joe

>>> "Gross, Mary" <GrossM@cder.fda.gov> 07/15/02 02:59PM >>>
Have I gotten your summary yet?

Mary

-----Original Message-----
From: Joseph Cranston [mailto:Joseph_Cranston@ama-assn.org]
Sent: Monday, July 08, 2002 1:15 PM
To: GrossM@cder.fda.gov
Cc: Carol Vargo
Subject: Re: FDA Public Meeting -- Barcoding Human Drugs and Biologics

Mary. The American Medical Association (AMA) requests permission to speak at the FDA Public Meeting, Bar Code Label Requirements for Human Drug Products, to be held at the Natcher Auditorium (NIH) on July 26th. I will be speaking on behalf of the AMA and expect the presentation to be between 5 and 10 minutes. Carol Vargo, Div. Federal Affairs, AMA DC office will also be attending We will give you a synopsis of the AMA presentation by this Friday, July 12th, as required in the Fed Reg notice

Could you confirm that you have received this email and that AMA will be placed on the list of speakers.

Thanks

Joe

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>>> "Gross, Mary" <GrossM@cder fda gov> 07/03/02 02:48PM >>>

Good afternoon

FDA is holding a public meeting on July 26 at Natcher Auditorium in Bethesda Maryland to discuss current regulatory activity relating to barcoding human drugs and biologics Your organizations have been identified as having expertise and interest in the development of this regulation. Part of this discussion will be arranged as panel discussions and your groups have been designated as appropriate to participate on either a health professional or industry panel I am including two attachments, one is a letter explaining the content and logistics of the public meeting and the other is the meeting notice that published in the Federal Register on June 18 This FR notice articulates a number of questions where FDA is seeking specific feedback

02N-0404
APE 114

We hope you will be able to join us for the meeting If your group would like to participate, please identify who will be representing your group Please remember that a written summary of presentations is due to the agency by July 12

Thanks and happy July 4!

Mary

<<barcoding-colleague invite.doc>> <<barcodefr.doc>>

BAR CODE LABEL REQUIREMENTS FOR HUMAN DRUG PRODUCTS

Summary of comments to be delivered by the American Medical Association at the FDA Public Meeting on July 26, 2002

- The American Medical Association (AMA) will support and encourage efforts to create and expeditiously implement a national machine-readable coding (bar coding) system for prescription and over-the-counter medicine packaging in an effort to improve patient safety.

- The AMA will state that extension of bar coding to other FDA-regulated products, such as blood products, vaccines, and certain medical devices appears to be a reasonable and attainable goal.

- The AMA does not have an official (organization) position on the specific elements that should be included in a Proposed Rule on bar coding.

- The AMA will encourage the FDA to balance the need to put uniform bar code standards into place as soon as possible to reduce medication errors with the need to not stifle innovation in bar code technology.

- As a start, the AMA will ask the FDA to consider the June, 2001 recommendations of the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) entitled, "Preventing and Standardizing Bar Coding on Medication Packaging: Reducing Errors and Improving Care."

- The AMA will conclude that the implementation of a national system for bar coding of commercially available drug products, and possibly other FDA-regulated products, should help physicians and other health professionals to decrease the number of medication errors and the harm to patients that is associated with these errors.

- The AMA will urge the FDA to quickly move forward with a Proposed Rule to require bar codes on drug product packaging.